

REMARKS

Applicants appreciate the examination of the present application as evidenced by the final Office Action dated May 15, 2008 (hereinafter, "Final Action"). Applicants further appreciate the indication that the previous enablement rejection of Claim 1 has been withdrawn.

Applicants also wish to thank the Examiner for the telephone interview with Applicant's attorney, Shawna Cannon Lemon, on October 14, 2008 (hereinafter, "the interview"). The participants discussed the pending application, and proposed claim amendments. In view of the helpful and constructive dialog expressed during the interview, Applicants set forth herein amendments and remarks that support the patentability of Claims 1, 2, 6-10, 12-16, 25, 28 and 31-37 pending upon entry of the present Amendment.

More specifically, Applicants have amended Claim 1 to recite that the aqueous liquid is a blood plasma product derived from plasma. Claim 12 has been amended to recite that the plasma is human plasma. Claim 31 has been amended to recite a plasma fraction. Support for these claim amendments can be found in the specification as originally filed, for example, page 4, lines 21-24 and Examples 1 and 4. As discussed during the interview, Applicants respectfully submit that this claim language further clarifies a distinction between the methods of the present invention and those of WO 96/05846 to Nebe (hereinafter, "Nebe"). In particular, as previously noted (*see, for example*, Applicants' Amendment submitted November 17, 2003), the starting material of Nebe is ground and extracted thymus tissue (homogenized calf thymus gland) containing cellular debris. The starting material of the present invention is, instead, derived from plasma (Claim 1) or a plasma fraction (Claim 31). Thus, the starting material of the present invention is a cell-free material. The nature of the starting material alone distinguishes the present invention from Nebe; however, the nature of the starting material further distinguishes the present invention from Nebe in that the pre-treatment steps of Nebe are required to remove cellular debris, and one of ordinary skill in the art would not have any reasonable expectation of any prion removal during the "prefiltration" stage of Nebe. It is the second ultrafiltration stage that is purportedly employed for prior removal, which stage is entirely different from the use of the depth filters as recited in the

pending claims. As previously made of record, Nebe specifically teaches that three filtration stages are required in order to remove the cellular debris *before* the resulting liquid can be subjected to the ultrafiltration step. As discussed with the Examiner, the methods recited in the pending claims *consist essentially of* the steps recited therein to the exclusion of the multiple stages required in Nebe.

Turning to GB 2 045 828 A to Ostreicher et al. (hereinafter, "Ostreicher et al."), as discussed with the Examiner, Ostreicher et al. discusses the use of depth filters to remove sub-micron contaminants such as bacteria, viruses or pyrogens from contaminated liquids. These contaminants are not the same as, or even similar to prion agents, which are protein molecules. Accordingly, the *submicron* contaminants discussed in Ostreicher et al. would not be expected to simulate *soluble prion protein* in the presence of plasma proteins as provided by the present invention. Moreover, one of ordinary skill in the art would not be motivated to replace the nylon filters used as prefilters in Nebe with the depth filters described in Ostreicher et al. absent the teachings of the present application to supply the specific teachings regarding the specific starting material, filter material and pore size and process steps as recited in the pending claims.

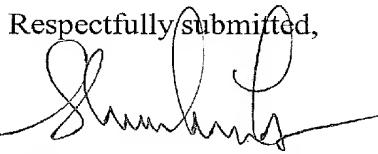
To further clarify the present invention, Applicants have added new Claims 33-36. Support for these claims can also be found in the specification and the claims as previously presented.

At least in view of the foregoing remarks and amendments presented herein, Applicants respectfully submit that Claims 1, 2, 6-10, 12-16, 25, 28 and 31-37 are not obvious in view of the combination of Nebe and Ostreicher et al., and Applicants submit that the claims are patentable over the cited references. Accordingly, Applicants respectfully request withdrawal of the outstanding rejection of the claims under 35 U.S.C. § 103 in view of the cited references.

In re: Welch et al.
Serial No.: 09/889,645
Filed: January 24, 2002
Page 8 of 8

CONCLUSION

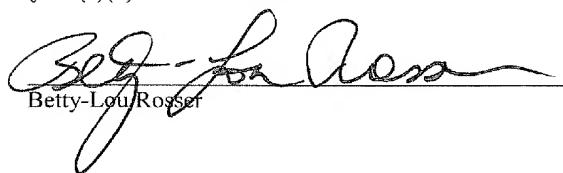
Accordingly, Applicants submit that the present application is in condition for allowance and the same is earnestly solicited. The Examiner is encouraged to telephone the undersigned at 919-854-1400 for resolution of any outstanding issues.

Respectfully submitted,

Shawna Cannon Lemon
Registration No. 53,888

USPTO Customer No. 20792
Myers Bigel Sibley & Sajovec
Post Office Box 37428
Raleigh, North Carolina 27627
Telephone: 919/854-1400
Facsimile: 919/854-1401

CERTIFICATION OF TRANSMISSION

I hereby certify that this correspondence is being transmitted via the Office electronic filing system in accordance with § 1.6(a)(4) to the U.S. Patent and Trademark Office on October 15, 2008.


Betty-Lou Rosser